Docket No.: C1037.70045US00

(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Arthur M. Krieg

Serial No.:

10/613,228

Confirmation No.:

4680

Filed:

July 3, 2003

For:

NUCLEIC ACID COMPOSITIONS FOR STIMULATING

IMMUNE RESPONSES

Examiner:

N. M. Minnifield

Art Unit:

1645

Certificate of Electronic Filing Under 37 CFR 1.8

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being transmitted via the Office electronic filing system in accordance with § 1.6(a)(4).

Dated: May 27, 2009

(Nicole Millette Lapomardo)

COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, VA 22313-1450

APPLICATION FOR PATENT TERM ADJUSTMENT UNDER 37 CFR §1.705

Dear Madam:

In accordance with 37 CFR §1.705(b), Applicant requests reconsideration of the patent term adjustment ("PTA") for U.S. Application No. 10/613,228 ("the '228 Application"). Applicant provides, below, a statement of the facts involved, specifying the correct PTA and the bases under 37 CFR §1.702 for the adjustment, the relevant dates for which adjustment is sought, and the adjustment to which the patent is entitled.

1. On 02/27/2009, the U.S. Patent and Trademark Office ("USPTO") mailed a Notice of Allowance and Determination of Patent Term Adjustment (Exhibit 1) for U.S. Application No. 10/613,228, which indicated that the '228 Application was entitled to a PTA of 0 days.

2. According to the Patent Term Adjustments page (Exhibit 2) of the Patent Application Information Retrieval (PAIR) system, the USPTO accorded the '228 Application a PTA of 110 days for delays that occurred at the USPTO, but reduced the PTA to 0 days because Applicant had allegedly incurred 385 days of delay.

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- 3. Applicant submits that the correct PTA should be 863 days, which is the net USPTO delay of 1248 days minus the apparent net Applicant delay of 385 days.
- 4. The difference between what Applicant submits is the correct PTA (863 days) and what the Notice of Allowance and Determination of Patent Term Adjustment states is the PTA (0 days) results from the USPTO's failure to issue the '228 Application within three years of its actual filing date, i.e. by 07/03/2006. *See* 35 U.S.C. § 154(b)(1)(B). The USPTO has not included this delay in its calculation of the PTA shown in the PAIR system.
- 5. Although the issue date of the '228 Application is unknown, the Notice of Allowance and Determination of Patent Term Adjustment assumes that the patent will issue on 09/08/2009, which is the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of the Notice. The period of delay thus began on the first day following the end of the three-year period (07/04/2006), will conclude on the assumed issue date of 09/08/2009, and results in a USPTO delay of 1163 days.
- 6. The net USPTO delay of 1248 days is the sum of the delay for failure to issue the '228 Application within the 3-year period (1163 days) and the USPTO delay periods shown in PAIR (110 days) minus the number of days these periods overlap on the calendar (25 days). *See Wyeth v. Dudas*, 580 F. Supp. 2d at 138, 141 (D.D.C. 2008) (holding that the "only way that periods of time can 'overlap' is if they occur on the same day"). The periods of overlap occurred from 02/28/2007 through 03/21/2007 (22 days) and from 08/18/2008 through 08/20/2008 (3 days).
- 7. A terminal disclaimer was not filed in this case and the '228 Application is not subject to a terminal disclaimer.

Docket No.: C1037.70045US00

Conclusion

Based on the foregoing, Applicant respectfully submits that the correct PTA should be 863 days and not 0 days as listed in the Notice of Allowance and Determination of Patent Term Adjustment. The 863 days of PTA results from the USPTO's failure to issue the '228 Application within 3 years of its filing date.

Applicant submits \$200.00, which is the fee set forth in 37 CFR § 1.18(e) for filing an application for PTA. If there is any additional fee occasioned by this application and request that is not covered by the enclosed fee, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,

Maria A. Trevisan

Registration No. 48,207

WOLF, GREENFIELD & SACKS, P.C.

Federal Reserve Plaza 600 Atlantic Avenue

Boston, MA 02210-2206

617.646.8000

Date: May 27, 2009

x05.27.09



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

23628

7590

02/27/2009

WOLF GREENFIELD & SACKS, P.C. 600 ATLANTIC AVENUE BOSTON, MA 02210-2206

EXA	AMINER
MINNIFI	ELD, NITA M
ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 02/27/2009

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,228	07/03/2003	Arthur M. Krieg	C1037,70045US00	4680

TITLE OF INVENTION: NUCLEIC ACID COMPOSITIONS FOR STIMULATING IMMUNE RESPONSES

APPLN, TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$300	\$0	\$1810	05/27/2009

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

- A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.
- B. If the status above is to be removed, check box 5b on Part B Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

- A. Pay TOTAL FEE(S) DUE shown above, or
- B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.
- II. PART B FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.
- III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for

maintenance fee notifications. Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission. CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address) 23628 7590 02/27/2009 Certificate of Mailing or Transmission WOLF GREENFIELD & SACKS, P.C. I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below. 600 ATLANTIC AVENUE BOSTON, MA 02210-2206 (Depositor's name (Signature) (Date CONFIRMATION NO. ATTORNEY DOCKET NO. FIRST NAMED INVENTOR APPLICATION NO. FILING DATE C1037.70045US00 4680 10/613.228 07/03/2003 Arthur M. Krieg TITLE OF INVENTION: NUCLEIC ACID COMPOSITIONS FOR STIMULATING IMMUNE RESPONSES SMALL ENTITY ISSUE FEE DUE PUBLICATION FEE DUE PREV. PAID ISSUE FEE TOTAL FEE(S) DUE DATE DUE APPLN, TYPE 05/27/2009 NO \$1510 \$300 \$1810 nonprovisional **EXAMINER** ART UNIT CLASS-SUBCLASS 514-044000 MINNIFIELD, NITA M 1645 1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363). 2. For printing on the patent front page, list (1) the names of up to 3 registered patent attorneys ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached. or agents OR, alternatively, (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required. listed, no name will be printed. 3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type) PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment. (A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY) ☐ Individual ☐ Corporation or other private group entity ☐ Government Please check the appropriate assignee category or categories (will not be printed on the patent): 4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above) 4a. The following fee(s) are submitted: ☐ Issue Fee A check is enclosed. Publication Fee (No small entity discount permitted) Payment by credit card. Form PTO-2038 is attached. The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any Advance Order - # of Copies _ overpayment, to Deposit Account Number 5. Change in Entity Status (from status indicated above) b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2). a. Applicant claims SMALL ENTITY status, See 37 CFR 1.27. NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office. Authorized Signature Date ___ Typed or printed name _ Registration No. _

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,228	07/03/2003	Arthur M. Krieg	C1037.70045US00	4680
23628	7590 02/27/2009		EXAM	IINER
WOLF GREET	NFIELD & SACKS, P.	C.	MINNIFIEL	.D, NITA M
600 ATLANTIC			ART UNIT	PAPER NUMBER
BOSTON, MA	02210-2206		1645	
			DATE MAILED: 02/27/200	Q

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

5/22/2009

Exhibit 2

10/613,228	NUCLEIC ACID COMPOSITIONS	FOR	STIMULATING IMMUNE RESPONSES	7:-30	05-22-2009::13:44:37
Patent Term Adjustments	djustments				
Patent Term Adju	Patent Term Adjustment (PTA) for Application Nu	Number: 10/613,228			
Filing or 371(c) Date:	ate:	07-03-2003	USPTO Delay (PTO) Delay (days):		110
Issue Date of Patent:	ent:	ŧ	Three Years:		ı
Pre-Issue Petitions (days):	s (days):	0+	Applicant Delay (APPL) Delay (days):		385
Post-Issue Petitions (days):	ns (days):	0+	Total PTA (days):		0
USPTO Adjustment(days):	ıt(days):	0+	Explanation Of Calculations		
Patent Term A	Patent Term Adjustment History				
Date	Contents Description			PTO(Days)	APPL(Days)
02-27-2009	Mail Notice of Allowance				•
02-26-2009	Reference capture on IDS	(0			
02-26-2009	Document Verification				
02-26-2009	Examiner's Amendment Communication	Communication			
10-28-2008	Examiner Interview Summary Record (PTOL - 413)	mary Record (PTOL - 41	(5)		
02-26-2009	Notice of Allowance Data Verification Completed	Verification Completed			
02-26-2009	Case Docketed to Examiner in GAU	ner in GAU			
12-22-2008	Information Disclosure Statement considered	tatement considered			
12-22-2008	Reference capture on IDS	(0			
12-22-2008	Information Disclosure Statement (IDS) Filed	tatement (IDS) Filed			32
12-22-2008	Information Disclosure Statement (IDS) Filed	tatement (IDS) Filed			*
12-07-2008	Date Forwarded to Examiner	iner			(
11-20-2008	Response to Election / Restriction Filed	estriction Filed			(
11-20-2008	Miscellaneous Incoming Letter	-etter			
11-20-2008	Request for Extension of Time - Granted	Time - Granted			
08-20-2008	Mail Restriction Requirement	nent		М	
08-18-2008	Requirement for Restriction / Election	ion / Election		*	
06-11-2008	Date Forwarded to Examiner	iner		*	
04-17-2008	Response after Non-Final Action	l Action			93
04-17-2008	Request for Extension of Time - Granted	Time - Granted			Çu z

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07-27-2005	Response after Non-Final Action
07-27-2005	Request for Extension of Time - Granted
03-21-2005	Information Disclosure Statement (IDS) Filed
03-21-2005	Information Disclosure Statement (IDS) Filed
03-25-2005	Mail Non-Final Rejection
03-21-2005	Non-Final Rejection
10-27-2004	Reference capture on IDS
10-27-2004	Information Disclosure Statement (IDS) Filed
10-27-2004	Information Disclosure Statement (IDS) Filed
01-12-2005	Date Forwarded to Examiner
12-27-2004	Response to Election / Restriction Filed
12-27-2004	Workflow incoming amendment IFW
11-26-2004	Mail Restriction Requirement
11-24-2004	Requirement for Restriction / Election
07-22-2004	IFW TSS Processing by Tech Center Complete
12-18-2003	Preliminary Amendment
04-29-2004	Reference capture on IDS
04-29-2004	New or Additional Drawing Filed
04-29-2004	Information Disclosure Statement (IDS) Filed
04-29-2004	Information Disclosure Statement (IDS) Filed
07-21-2004	Case Docketed to Examiner in GAU
04-29-2004	New or Additional Drawing Filed
02-03-2004	Application Return from OIPE
02-03-2004	Application Return TO OIPE
02-03-2004	Application Is Now Complete
02-02-2004	Application Dispatched from OIPE
02-02-2004	Application Is Now Complete
12-16-2003	Payment of additional filing fee/Preexam
01-06-2004	CRF Is Good Technically / Entered into Database
12-16-2003	CRF Disk Has Been Received by Preexam / Group / PCT

5/22/2009

07-03-2003	Drawing Preliminary Amendment	*
07-03-2003	A document that contains, at least in part, a written description of an invention, and of the manne	\$
07-03-2003	Claim Preliminary Amendment	÷
12-16-2003	CRF Disk Has Been Received by Preexam / Group / PCT	dia.
12-16-2003	A statement by one or more inventors satisfying the requirement under 35 USC 115, Oath of the Applic	*
10-16-2003	Notice MailedApplication IncompleteFiling Date Assigned	*
07-03-2003	CRF Disk Has Been Received by Preexam / Group / PCT	\$
10-07-2003	Cleared by OIPE CSR	*
09-09-2003	IFW Scan & PACR Auto Security Review	(
08-08-2003	CRF Does Not Match Application Specification Applicant Must Correct	ŧ.
07-03-2003	CRF Disk Has Been Received by Preexam / Group / PCT	(iz
07-03-2003	Initial Exam Team nn	lips

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